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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,693	09/25/2003	Chunhua Yan	CL000685-CON	4287

25748 7590 10/20/2004

CELERA GENOMICS CORP.
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,693

Applicant(s)

YAN ET AL.

Examiner

Christian L Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: CRF paper.

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DETAILED ACTION

Election/Restriction

1. Applicants' election of Group I and cancellation of claims corresponding to non-elected Groups II and III, claims 10-16, in the reply filed on September 02, 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is still deemed proper and is therefore made FINAL.
2. Claims 1-9, drawn to an isolated nucleic acid molecule, vector, and host cell, are pending and under consideration in this Office Action.
3. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.
4. The paper copy and computer readable form (CRF) of the Sequence Listing filed 09/25/2003 have been received and have been processed by the Scientific and Technical Information Center (STIC). Minor corrections were made by STIC to the Sequence Listing to correct formatting errors, specifically, line <140> is corrected to state the instant application serial number 10/669,693; line <141> is corrected to state the current filing date of 9/25/2003; line <150> is corrected to state prior application serial number 09/748, 127; and line <151> is corrected to state a prior filing date of 12/27/2000.
5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Isolated nucleic acid molecule encoding a human cytochrome p450.

Claim Objections

6. Claim 2 is objected to because of the following informality: claim 2 should recite the phrase "comprising **the** nucleic acid molecule" instead of "comprising a nucleic acid molecule" since the claim depends from independent claim 1. Appropriate correction is required.

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Claim Rejections - 35 U.S.C. § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility.

The specification discloses an isolated nucleic acid molecule that consists of the nucleotide sequence of SEQ ID NO: 1 and encodes a protein having the deduced amino acid sequence of SEQ ID NO: 2. The specification discloses a nucleic acid molecule that consists of the genomic nucleotide sequence of SEQ ID NO: 3 and contains the nucleotide sequence of SEQ ID NO: 1 that has several inserted introns.

Based on computer programs that search databases for similarities to the disclosed nucleotide and amino acid sequences, the specification assigns the protein having the deduced amino acid sequence of SEQ ID NO: 2 as a protein that is a member of "drug-metabolizing enzyme family of proteins" and is related to the cytochrome p450 (CYP) drug-metabolizing enzyme subfamily (see specification p. 9, lines 10-13). However, Figure 2C of the disclosure shows that Blast computer searches in the databases detected only a 50% identity between SEQ ID NO:2 and the amino acid sequence of a rabbit cytochrome p450.

The specification does not disclose any enzyme assays that demonstrate that the protein having the deduced amino acid sequence of SEQ ID NO: 2 has cytochrome p450 activity. The specification does not disclose a specific biological function of the protein having the deduced amino acid sequence of SEQ ID NO: 2. The specification does not disclose that any homology to a reference protein known in the art is a disclosure that the claimed protein automatically has the properties and biological function of the reference protein relied upon. Furthermore, the specification's assignment of the protein as being related to cytochrome p450 drug-metabolizing enzyme subfamily is not a specific asserted utility, but is, instead, a general asserted utility since many proteins that are related in any manner to cytochrome p450 would be included in this drug-metabolizing enzyme subfamily, such as a protein that has amino acid sequence similarity to cytochrome p450 but has completely different biological function.

The state of the state of the art in protein function prediction from protein amino acid sequence and structure is reviewed by Whisstock et al. (Q Rev Biophys. 2003 Aug;36(3):307-40). Whisstock et al. teach (1) protein function prediction is a difficult problem since homologous proteins often have different and multiple functions; (2) methods for inferring function based on similarity in sequence and/or structure between an unknown protein and one or more well-understood proteins is tenuous and only provide guesses at function; (3) protein

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function predictions suggest function but do not determine function; (4) the most useful effect of protein function prediction is to guide laboratory experimentation to confirm, refute, or correct the prediction; and (5) protein function prediction from protein sequence and structure is useful but is not a substitute for laboratory experimentation (see entire publication, especially pp. 321-335).

A "specific utility" is specific to the subject matter claimed which contrasts with a general utility that would be applicable to the broad class of the invention. "Substantial utility" is one that provides a specific benefit in currently available form at the time of filing of the invention. Utilities that require or constitute carrying out further research to identify and/or reasonably confirm a specific use are not substantial and do not provide a specific benefit. See MPEP 2107.01

In view of the disclosure and state of the art in protein function prediction stated above, one of ordinary skill in the art would not recognize that claims 1-9 have a specific or substantial asserted utility or a well established utility since the only recognized utility of the claimed nucleic acid molecule and protein is to carry out further research to identify and/or reasonably confirm the specific biological function associated with the claimed nucleic acid molecule and protein.

Thus, the nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 lacks utility since the protein encoded having the deduced amino acid sequence of SEQ ID NO:2 has no specific or substantial asserted utility or a well established utility. Since the nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1 lacks utility, then the genomic nucleotide sequence of SEQ ID NO: 3 which contains the nucleotide sequence of SEQ ID NO: 1 also lacks utility. Furthermore, since the nucleic acid molecules of SEQ ID NO: 1 and SEQ ID NO: 3 lack utility, then the claimed vectors and host cells and method of making the claimed protein using these claimed nucleic acid molecules also lack utility

9. Claims 3 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claim 3, as written, do not sufficiently distinguish over host cells as they exist naturally because the claim does not particularly point out any non-naturally occurring differences between the claimed product and the naturally occurring product. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

The claims should be amended to indicate the hand of the inventor, e.g., by reciting "an isolated host cell transformed with the vector of claim 2". See MPEP 2105.

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Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 4, 8, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 4 recites a process for producing a “polypeptide”, but the final method step recites recovering a “peptide” from the host cell. There is not antecedent basis for a “peptide” in line 3 of claim 4 because the preamble of claim 4 recites a process for producing a “polypeptide”. Furthermore, it is uncertain whether the claim is directed toward a process for producing a polypeptide or a peptide which are two different substances.

In addition, since the claimed process uses a host cell containing a vector comprising the nucleic acid molecule of claim 1, it is unclear as to whether the claimed process, as written, is directed toward producing a polypeptide encoded by the nucleic acid molecule of claim 1 or directed toward producing any other polypeptide. Clarification regarding these concerns is requested.

The phrase “may be expressed” in claim 8 renders the claim vague and indefinite because it is not clear whether or not the protein of SEQ ID NO: 2 is claimed to be actually expressed by a cell transformed with the claimed vector. Claim 9 is also rejected because it does not correct

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the defect of claim 8.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Policky et al. (WO 01/79468 A2, published Oct. 25 2001; PTO 892).

Policky et al. teach an isolated nucleic acid molecule of SEQ ID NO: 16 which encodes a protein comprising the amino acid sequence of SEQ ID NO: 2 of the instant invention (see enclosed alignment). Thus, the reference teaching anticipates claim 1.

Policky et al. teach nucleic acid vectors including viral vectors that contain promoters and the reference nucleic acid molecule of SEQ ID NO: 16 in proper orientation and correct reading frame such that the protein of SEQ ID NO: 2 of the instant invention can be expressed in a transformed host cell (see entire publication, especially p. 41, line 30 to p. 42, line 6; and p. 51 line 31 to p. 52, line 2). Thus, the reference teachings anticipate claims 2 and 7-9.

Policky et al. teach host cells containing said vector and process for producing a polypeptide by culturing the said host cell under conditions for production of the polypeptide of SEQ ID NO: 2 of the instant invention, and recovering the said polypeptide from the said host cell culture (see entire publication, especially p. 51, line 15 to p. 55, line 22). Thus, the reference teachings anticipate claims 3 and 4.

WO 01/79468 A2 claims priority to US Provisional Application No. 60/200,185, filed 04/28/2000, and is considered prior art, as defined by 35 U.S.C. 102(e), because US Provisional Application No. 60/200,185 discloses and has support for the nucleotide sequence of SEQ ID NO: 16 which encodes the protein of amino acid sequence of SEQ ID NO: 2 of the instant invention and vectors, host cells, and method for making the said protein of the instant invention.

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Conclusion

16. No claims are allowed.
17. The following reference made of record and not relied upon is considered pertinent to applicant's disclosure: Accession XP_341810 discloses a protein from rat which is predicted to encode a cytochrome p450 having an amino acid sequence identity of 46% to SEQ ID NO: 2.
18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christian L. Fronda
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IFWO

**CRF Errors Edited by the STIC Systems
Branch**

Serial Number: 10/669,693

CRF Edit Date: 10/7/03
Edited by: RG

___ Realigned nucleic acid/amino acid numbers/text in cases where the sequence text "wrapped" to the next line

___ Corrected the SEQ ID NO. Sequence numbers edited were

ENTERED

___ Inserted or corrected a nucleic number at the end of a nucleic line. SEQ ID NO's edited:

☒ Deleted: ___ invalid beginning/end-of-file text ; ___ page numbers

___ Inserted mandatory headings/numeric identifiers, specifically:

___ Moved responses to same line as heading/numeric identifier, specifically:

☒ Other: <140>, <141> corrected <150> <151>